

# FDA Warns On Opioids in Children's Cough and Cold Syrups



By Julianna LeMieux — May 1, 2017



The FDA has been busy lately, from [protecting children from fake autism treatments](#) [1] to putting enough pressure on the makers of [homeopathic teething remedies to result in a recall of the products](#) [2].

But the agency does not intend to stop there. It is now cracking down on the use of opioid-containing drugs for children. But, is this an overreaction? Maybe.

The FDA has restricted the use of prescription pain and cough medicines with codeine or tramadol (for pain) for children and breastfeeding mothers. They want to remind health care professionals that tramadol **(1)** and single-ingredient codeine medications are FDA-approved for use only in adults.

These medicines that can pose serious risks for adults (when a large dose is taken) are riskier in children under 12 years old. The primary concern is slowed or difficult breathing which can be life threatening. This risk does not come from codeine itself but rather, its metabolic byproduct - morphine. Different people have different rates of metabolism **(2)**. Some are "hyper responders" - they metabolize drugs very quickly. [Codeine is one of the drugs that affects hyper responders](#) [3]. If the drug is broken down too quickly, the morphine level in the body can become too high, too fast - resulting in a dangerous situation. There is no easy way to predict how quickly any person will break down these medications.

The signs to look for are slow or shallow breathing, difficulty or noisy breathing, confusion, excessive sleepiness, trouble breastfeeding, or limpness.

The FDA is requiring the following changes to the labels of all prescription medicines containing

these drugs. These restrictions are in addition to the 2013 restrictions put into place for children younger than 18 years, specifically speaking to the treatment of pain following the removal of tonsils or adenoids.

- A *Contraindication* (the FDA's strongest warning) to the labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol, should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

The FDA is not making this statement without extensive evidence. They have studied decades of cases of adverse events from these medications, from 1969 to 2015. There were 64 cases of serious breathing problems, including 24 deaths. In addition, there are many cases of both sleepiness and breathing difficulties in babies breastfeeding from women on these medications.

But, is this an overreaction? Twenty-four deaths in 49 years means that one child dies every two years. There are [74 million children](#) <sup>[4]</sup> in the US, which makes the risk of death in an average year about one in 150,000,000. At the Council, one of our goals is to put risk in perspective. This one is very low.

The FDA does not even recommend over the counter (non-opioid containing) cold and cough medicines for children younger than 2. They state that most coughs are not serious and will get better on their own, without treatment **(3)**. And, with the intensity of the growing opioid epidemic reaching frightening heights - that's probably good advice for everyone.

If you wish to report side effects involving codeine-and tramadol- containing medicines to the FDA MedWatch program complete and submit the report [Online](#) <sup>[5]</sup>.

### List of Prescription Codeine and Tramadol Pain and Cough Medicines

Medicines Containing Codeine	Medicines Containing Tramadol	
	Codeine Sulfate	Conzip
	Butalbital, Acetaminopen, Caffeine, and Codeine phosphate	Ultracet
	Fiorinal with codeine	Ultram
	Soma Compound with codeine	Ultram ER

Tylenol  
Generic products  
with  
containing tramadol  
codeine

Promethazine with codeine (cough)	
Prometh VC with codeine (cough)	
Triacin-C (cough)	
Tuxarin ER (cough)	
Tuzistra-XR (cough)	
Generic products containing codeine	
<b>Medicines Containing Dihydrocodeine</b>	
Synalgos-DC	

Notes:

(1) Tramadol (brand name Ultram) is an atypical opioid. It is considerably less potent than hydrocodone (Vicodin) or oxycodone (Percocet). Its abuse potential is much lower (95 percent) than that of typical opioids.

(2) Codeine (like almost all drugs) is metabolized in the liver by enzymes called CYPs, short for cytochrome P450.

(3) This is normally true, but not necessarily so for asthmatics. Coughing can exacerbate asthma, which causes more coughing. There are legitimate reasons to suppress coughs.

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[1] <http://www.acsh.org/news/2017/04/17/fda-warns-about-fake-autism-treatments-11143>

[2] <http://www.acsh.org/news/2017/04/14/finally-recall-hylands-homeopathic-teething-tablets-11132>

[3] <https://www.ncbi.nlm.nih.gov/books/NBK100662/>

[4] <http://www.aecf.org/resources/the-changing-child-population-of-the-united-states/>

[5] <https://www.accessdata.fda.gov/scripts/medwatch/>